

REMARKS

Summary Of The Office Action & Formalities

Status of Claims

Claims 1-22 are all the claims pending in the application. By this Amendment, Applicant is amending claims 1, 21 and 22. No new matter is added.

Additional Fees

Submitted herewith is a Petition for Extension of Time with fee.

Drawings

The drawings were received on 03/09/2010. The Examiner permitted the entry of these drawings only to the extent that it shows a generic inhaler. None of its structural limitations, features, and any reference to the details of the inhaler will not be entered.

Applicant thanks the Examiner for acknowledging and accepting the drawings filed on March 9, 2010.

Art Rejections

1. Claims 1-4, 7-9, 11, 13 and 20-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekelius et al. (US 6,637,431 (Ekelius)) in view of Razeti (US 2003/0108714).

2. Claim 1 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekelius in view of Razeti and further in view of Fuller et al. (US 2002/0008046 (Fuller)).

3. Claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekelius in view of Razeti and further in view of Lippert (US 4,938,414).

Applicant respectfully traverses.

Claim Rejections - 35 U.S.C. § 103

1. Claims 1-4, 7-9, 11, 13 And 20-22 Over Ekelius et al. (US 6,637,431) In View Of Razeti (US 2003/0108714).

In rejecting claims 1-4, 7-9, 11, 13 and 20-22 over Ekelius et al. in view of Razeti, the grounds of rejection state:

In reference to Claim 1

Ekelius discloses a blister strip (12) for use in a fluid or powder inhaler, and including a plurality of blisters (13), each formed by a reservoir (created by 19) including an opening (at the top of 19, see Figure 10) that is sealed in leaktight manner by a tearable layer (20) and a cavity layer (18) that is provided with cavities (19) forming the blister walls.

Ekelius discloses the claimed invention as discussed above with the exception of the following claimed limitations that are taught by Razeti: a base layer (19) that is provided with openings (23, Figure 5) forming the openings of the blisters, and said tearable layer (20, of Ekelius see above) comprising a first tearable-layer portion (21) that is disposed between said base layer (19) and said cavity layer (18 of Ekelius), and a second tearable-layer portion (22) that is disposed on the opposite side of said base layer, said first and second tearable-layer portions being connected together at each opening of the base portion (see figures 4 and 5, where the first and second tearable layers (21 and 22 are connected at 23 and 24).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti so that the tearable layer in Ekelius is modified with features of Ekelius, in order to make the container opening operations convenient for users, as taught by Razeti (column 1, paragraphs 0011).

...

In reference to Claim 21

Ekelius discloses a blister strip (12) for use in a fluid or powder inhaler, comprising: a blister (13) formed

by a reservoir (created by 19) comprising a blister opening (at the top of 19, see Figure 10); a first tearable layer (20) sealing the blister opening (see Figure 10).

Ekelius teaches the claimed invention as discussed above with the exception of the following claimed limitations that are taught by Razeti: a base layer (19) above the first tearable layer (the first tearable layer 20 of Ekelius is replaced with 21 of Razeti) and comprising a base layer opening (23) corresponding to the blister opening (container opening 24); a second tearable layer (22) above the base layer and connected to the first tearable by a material connection (see Figure 5, 21 and 22) passing through the base layer opening so that, upon lifting the second tearable layer (22), an edge of the base layer opening tears the material connection formed between the first tearable layer and the second tearable layer (see figure 5 where lifting 22 tears the material connection formed at the opening), thereby unsealing the blister opening (see Figure 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti so that the tearable layer in Ekelius is modified with features of Ekelius, in order to make the container opening operations convenient for users, as taught by Razeti (column 1, paragraphs 0011).

Office Action at pages 2-7.

In response to Applicant's arguments filed March 9, 2010, Examiner states:

Applicant's arguments, filed 03/09/2010, with respect to claim 1 have been fully considered and are not persuasive.

In reference to Claims 1-4, 7-9, 11, 13 and 20-22

In response to applicant's argument that Razeti (US 2003/0108714) is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the sealing layer of Razeti can be applied to seal a receptacle (i.e. the receptacle of Ekelius). Both references are in the art of retaining

and dispensing ingestible articles and there is a logical combination between the two cited references.

Applicant further argues that the neither Ekelius nor Razeti teach a guaranteed dispensing of the entire dose and to allow breath-actuation. The Ekelius reference teaches an inhaler that is capable of dispensing an entire does of medication (i.e. a user can inhale the contents within the blister, col. 1, ll. 29-38).

Applicant further argues that Razeti's containers are individual and they are intended to be manually opened. The Razeti reference is cited to show the sealing layer feature, which can be combined with the Ekelius reference so that the sealing layer of Ekelius is replaced with the sealing layer of Razeti. When the inhaler of Ekelius is in use, the modified Ekelius in view of Razeti would still perform the task of dispensing a dose of medication. In as much as the applicant has claimed the inhaler in combination with the blister strips, the prior shows the claimed limitations of applicant's invention.

Applicant argues that elements 21 and 22 are clearly two pieces bonded together thus cannot be a one-piece construction. In as much as the applicant has claimed the one-piece construction, element 21 and 22 do form a one-piece construction when they are bonded together.

Office Action at pages 12-13.

Claims 1 and 21 have been amended to recite that the product inside the blister is a pharmaceutical powder and that the connection between the first and second tearable layers is provided all around the opening. As explained, for example, in Applicant's specification at page 7, lines 11-18, this feature permits one to open the blister opening in a clean and accurate manner without any residual portions of the tearable layer on the edges of the opening.

Applicant maintains that the combination of Ekelius (disclosing a blister pack, not a blister strip as claimed) with Razeti (disclosing a food container) to obtain a blister strip for pharmaceutical powders is not possible, let alone obvious, for the reasons discussed in Applicant's last response.

Indeed, even, for the sake of argument, if one were to combine Ekelius with Razeti, any resulting combination would fail to have a strip (which is an elongate member supporting the reservoirs one behind the other). Further, any such combination would fail to have a blister opened all around its opening surface.

Ekelius discloses the use of a suction tube to *penetrate* inside the blister cavity, without requiring that the blister cavity to be fully opened (which is not necessary or desirable, as the blister content escapes from the inside through the suction tube). Razeti discloses the use of a small hole in the central part of the reservoir's closure layer. There is simply no motivation or other rationale for modifying the Razeti structure to provide a complete opening of the surface of the reservoir's opening. To the contrary, given the differences in the devices and the scaling structures uniquely designed for each device, even if one skilled in the art would have considered Ekelius and Razeti together, the skilled artisan would have been *led away* from the alleged combination.

For at least the foregoing reasons, claims 1 and 21 and claims dependent therefrom are patentable.

Furthermore, regarding claim 22, "integral one-piece construction" is a term having a clearly recognized meaning that excludes two pieces bonded together. Nevertheless, Applicant has further amended the claim to clarify this feature.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

/Raja Saliba/
Raja Saliba
Registration No. 43,078

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: November 19, 2010